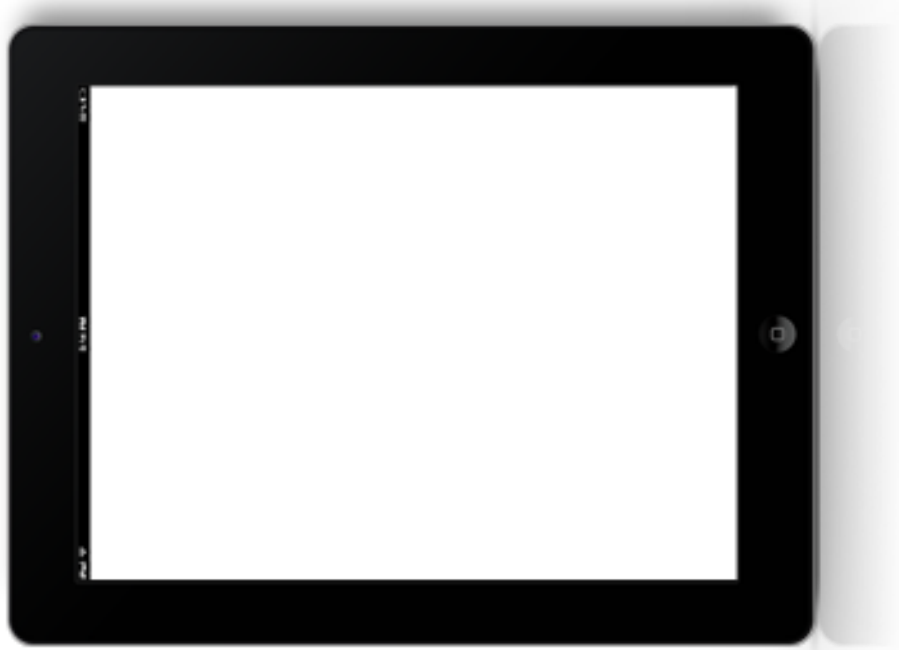

- 6.1 Actions to address risks and opportunities
- 6.2 Quality objectives and planning to achieve them
- 6.3 Planning of changes.

6. PLANNING

Planning for the Quality Management System

6.1 Actions to address risks and opportunities

6.1.1
When planning for the QMS determine the ***risks and opportunities*** that need to be addressed to:

a) give assurance that the QMS can achieve its intended result(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects

d) achieve improvement.

definition

RISK

effect of uncertainty

6.1 Actions to address risks and opportunities

6.1.1
When planning for the QMS determine the ***risks and opportunities*** that need to be addressed to:

a) give assurance that the QMS can achieve its intended result(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects

d) achieve improvement.

6.1 Actions to address risks and opportunities

6.1.2
The organization shall plan:

- a) actions to address these risks and opportunities
- b) how to:
  1) integrate and implement the actions into its QMS processes
  2) evaluate the effectiveness of these actions.

Actions shall be proportionate to the potential impact on the conformity

6.2 Quality objectives and planning to achieve them

6.2.1

- The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

- The organization shall maintain documented information on the quality objectives.

6.2 Quality objectives and planning to achieve them

The quality objectives shall:

- a) be consistent with the quality policy;
- b) be measurable;
- c) take into account applicable requirements;
- d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) be monitored;
- f) be communicated;
- g) be updated as appropriate.

definition

POLICY

intentions and direction of an organization as formally expressed by its top management

definition

QUALITY POLICY

policy related to quality

definition

OBJECTIVE

result to be achieved

definition

QUALITY OBJECTIVE

objective related to quality

6.2 Quality objectives and planning to achieve them

The quality objectives shall:

- a) be consistent with the quality policy;
- b) be measurable;
- c) take into account applicable requirements;
- d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) be monitored;
- f) be communicated;
- g) be updated as appropriate.

6.2 Quality objectives and planning to achieve them

6.2.2

When planning how to achieve its quality objectives, the organization shall determine:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

6.3 Planning of changes

When the organization determines the need for changes to the QMS, the changes shall be carried out in a planned manner

The organization shall consider:

a) the purpose of the changes and their potential consequences
b) the integrity of the QMS
c) the availability of resources
d) the allocation or reallocation of responsibilities and authorities.